IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
Orlando Division

NORMAN MIERKE, Plaintiff, vs. WRIGHT MEDICAL TECHNOLOGY, INC., Defendant.	Case No. _____ **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, Norman Mierke, by his undersigned counsel, sues the Defendant, Wright Medical Technology, Inc., and alleges:

NATURE OF THE CASE

1. This is an action for damages which arise from injuries sustained by the Plaintiff, Norman Mierke, as the result of having been implanted with a defective Wright Medical Total Hip System ("the Device" or Wright Medical device") into his left hip that was designed, manufactured and sold by the Defendant, Wright Medical Technology, Inc.

THE PARTIES

2. Plaintiff, Norman Mierke, is a citizen of and domiciled in Cocoa, Brevard County, Florida.

3. At all relevant times, Defendant, Wright Medical Technology, Inc. ("hereinafter "Wright Medical" or "WMT" or "Defendant") was a Delaware corporation with its principal place of business in Memphis, Tennessee and is registered to do business in the State of Florida, and may be served with process by serving its registered agent at Corporation Service Company, 1201 Hays Street, Tallahassee, FL 32301-2525.

4. At all relevant times, Defendant, Wright Medical Technology, Inc., developed, manufactured, advertised, promoted, marketed, sold, and/or distributed defective Wright Medical Hip Systems, which included a metal Dynasty shell, a Dynasty polyethylene liner, a cobalt chromium (CoCr) Conserve femoral head, a cobalt chromium (CoCr Profemur modular neck and Profemur titanium alloy stem (hereinafter "the Device"), throughout the United States, including within the State of Florida, and specifically including to Plaintiff, Norman Mierke, or his implanting physician or to the hospital where the Device was implanted.

JURISDICTION AND VENUE

5. This is an action for damages which exceed the sum of $75,000.00, exclusive of interest, costs and attorney's fees.

6. At all relevant times, Plaintiffs were residents of, and domiciled in, the State of Florida and the Defendant is a Delaware corporation with its principal place of business in Tennessee, creating complete diversity of citizenship. Defendant, Wright Medical Technology, Inc. did significant business in Florida and was registered to do business in Florida, and Plaintiff's injuries, damages and treatment occurred in Brevard County, Florida. Accordingly, this Court has diversity jurisdiction pursuant to 28 U.S.C. Sec. 1332.

7. Pursuant to 28 U.S. C., Sec. 1391 (a) and (c), venue of this case is appropriate in the District Court of Florida in that a substantial portion of the events giving rise to this action occurred in Brevard County, Florida, and Plaintiff's injuries occurred and were treated exclusively in Brevard County, Florida.

STATEMENT OF FACTS APPLICABLE TO ALL COUNTS

The Profemur Total Hip Components

8. A total hip replacement replaces the body's natural hip joint with an artificial one,

usually made with metal and/or ceramic and plastic. A total hip replacement generally includes four components: an acetabular shell, an acetabular liner, a femoral head and a femoral stem. The femoral head is a metal or ceramic ball that is affixed to the top of the femoral stem. The femoral head forms the hip joint when it is placed inside the liner and acetabular shell. These conventional hip replacement prostheses typically last up to 20 years.

9. The total hip system at issue included a WMT Dynasty acetabular cup and liner, a WMT Conserve cobalt chromium femoral head, a WMT Profemur cobalt chrome (CoCr) modular neck that fit between the femoral head and the stem, and a WMT Profemur titanium alloy femoral stem.

10. WMT Profemur components have been manufactured and sold in the United States since 2001. Prior to 2009, both the Profemur modular neck and the Profemur stem were made of titanium alloy. However, in 2009, due to a myriad of complaints that the Profemur titanium modular necks were fracturing and/or failing and severely injuring patients, Wright Medical changed the composition of the Profemur modular necks from titanium to cobalt/chromium.

11. Wright Medical's design application of pairing two dissimilar metal alloys together (i.e. cobalt chromium neck with the titanium alloy stem) in a corrosive environment (the human body) created galvanic corrosion, not unlike that which would occur in a battery.

12. This corrosion at the junction at the trunnion between the Profemur CoCr modular neck and titanium alloy Profemur stem causes severe pain and swelling in the hip, permanent injury to the surrounding tissues, and failure of the total hip replacement which ultimately requires further surgery to repair and replace the total hip. Tissue destruction caused by the corrosion is often seen during surgery and can lead to permanent muscle loss and dysfunction.

In addition, metallosis or metal debris which results from the corrosion can enter the blood stream of the patient causing systemic injury.

13. In short, total hip systems which included these Profemur components presented an unreasonably high risk of premature failure due to corrosion, trunnionosis, and severe metallosis. Because of Defendant's defective design of the Wright Medical Profemur components, hundreds of patients, including the Plaintiff, Norman Mierke, have required revision surgery to replace the failed hip implants.

14. Even prior to 2009, when the cobalt chrome Profemur modular neck was cleared for marketing, Defendant knew that the Profemur modular neck, paired with the Profemur stem, created an unreasonably high risk of failure due to fretting corrosion and metallosis, and failed to notify or warn the United States FDA, the medical community or the general public of that risk.

15. In fact, on December 1, 2008, Wright Medical published a Safety Alert to Healthcare Professionals concerning the use of modular necks in hip replacement surgery, stating that it had received reports of some modular neck failures. However, the letter indicated that those failures involved mostly heavyweight males with long modular necks and patient activities such as heavy lifting and impact sports.

16. Nevertheless, Wright Medical continued to aggressively market and sell Profemur cobalt chrome modular long necks paired with the titanium Profemur stems, without warning of the unreasonably high risk of failure due to micromotion between the components, fretting corrosion and metallosis to patients.

17. Due to Defendant's failure to warn, or adequately warn, the medical community and the general public that the Profemur components presented a high risk of failure due to corrosion, metallosis and failure of the hips, Plaintiff, Norman Mierke was implanted with a

Wright Medical Total Hip System in 2014 which included a Profemur cobalt chrome modular neck and Profemur titanium stem, and suffered severe injury due to metallosis, which required total revision of the hip after only four years.

18. In August, 2015, Defendant (which had then been purchased by MicroPort) recalled the Profemur cobalt chrome modular long neck due to unexpected rate of postoperative fractures and failures due to corrosion at the trunnion, resulting in the need for revision surgery. However, the Profemur cobalt chromium short neck, which also failed due to corrosion at the trunnion remains on the market.

DEFECTIVE DYNASTY COMPONENTS

19. The Dynasty acetabular components that were implanted into Plaintiff consisted of a titanium alloy shell and A-Class poly liner, and were cleared for marketing by the FDA in June, 2006.

20. The Dynasty shell was designed to accept both metal liners and poly liners and were specifically indicated to be paired with Profemur modular necks.

21. Wright Medical touted these components to greatly increase the range of motion of the patient, and reduce wear and metal debris and also to reduce neck impingement and the possibility of dislocation.

22. The Dynasty components were defectively designed in that the poly liner broke apart and disintegrated after only four years of reasonably foreseeable use by the Plaintiff.

23. The Dynasty acetabular components were also defective in that proper and successful surgical placement is exceedingly difficult for even experienced and competent surgeons to accomplish in implanting the Device into patients.

24. Once the body was exposed to this Dynasty cup with the Dynasty poly liner and

cobalt chromium Conserve head and Profemur modular neck, the corrosion caused by the Profemur components began to eat away at the poly liner, breaking the liner down, causing it to migrate and allow the metal femoral head to articulate directly against the titanium cup. Not only were broken fragments of the liner floating loose within the hip, but the metal-on-metal articulation between the head and the shell created even more metallosis in the hip, with increased inflammation, severe pain, death of the surrounding tissue, bone loss and other severe injuries.

25. Since 2006, Defendants knew or should have known that the Wright Medical Total Hip, which included the Dynasty shell and Dynasty poly liner, coupled with a CoCr femoral head and Profemur modular neck, would fail early due to metal debris, thereby giving rise to unnecessary pain and suffering, debilitation, and the need for revision surgery to replace the defective devices with the attendant risk of complications from such further implant revision surgery in patients, including the Plaintiff, Norman Mierke.

26. The fact that the Profemur femoral components, coupled with the CoCr Conserve head and Dynasty poly liner created an unreasonably high risk of injury, unnecessary pain and suffering, and required revision surgery for implanted patients is a material fact.

27. Defendant failed to disclose this material fact to consumers, including the Plaintiff, Norman Mierke, and his implanting surgeon.

Reliance of the Plaintiff

28. At all relevant times, Defendant Wright Medical, took affirmative steps to prevent physicians and consumers, including the Plaintiff, Norman Mierke, from learning that the Profemur cobalt chrome neck posed an unreasonably high risk of failure due to micromotion with the Profemur stem, while aggressively marketing the components as safe and effective for

use in hip replacement surgeries. This concealment was made with the intent to induce Plaintiff, as well as other patients and physicians, to purchase the Wright Medical components and to prevent patients from discovering that they were being implanted with a defective Device.

29. Plaintiff and his implanting surgeon would have been able to discover the cause of his pain and disability or defects in the Profemur hip components earlier but for the fact that Defendant actively concealed these facts from physicians and patients, including Plaintiff, which led to a delay in discovery as well as unnecessary suffering for the Plaintiff.

30. In reliance upon Defendant's fraudulent concealment of material fact, Plaintiff's implanting surgeon selected, and Plaintiff purchased, the Wright Medical Profemur components as part of the total hip replacement that was implanted into his body. Had Plaintiff's surgeon known that the Device would fail early, thereby giving rise to unnecessary physical injury, pain and suffering, and the need for revision surgery to replace the Device, Plaintiff's surgeon would not have selected the Profemur hip components to implant into the Plaintiff. Had the Plaintiff known that the Profemur components would fail early, thereby giving rise to unnecessary physical injury, pain and suffering, and the need for revision surgery to replace the Device, Plaintiff would not have purchased the Wright Medical Profemur components.

31. Defendant made representations of fact and/or promises through its advertisements, labeling, detailing, marketing and/or promotion of the Profemur Device to healthcare professionals, the FDA, Plaintiff, and the public by representing that the Profemur cobalt chrome modular neck coupled with the Profemur titanium alloy stem was safe, effective, fit, and proper for its intended use in order to induce patients and surgeons to purchase and use the Device.

32. These representations and/or promises regarding the Device were false and

Defendant knew they were false at the time Plaintiff was implanted with his Profemur components.

33. Plaintiff's implanting surgeon unknowingly communicated Defendant's false representations to the Plaintiff concerning the safety and efficacy of the Device and Plaintiff relied upon those false representations to his detriment.

Plaintiff's Implant

34. On or about April 7, 2014, Plaintiff, Norman Mierke, underwent a left total hip replacement and received a Total Hip System in his left hip which included Wright Medical hip components that were designed, manufactured, tested, labeled, marketed, distributed and/or sold by the Defendant. Said total hip replacement was performed at Parrish Medical Center in Titusville, Florida by Ramy S. Hanna, MD for post-traumatic arthrosis.

35. At that time, Plaintiff was implanted with a Wright Medical Total Hip System, with a 56mm Dynasty titanium shell, Ref. DSPC-GF56, Lot 1532952; a 40mm Dynasty poly liner, Ref. DLXPLF40, Lot 1537819; a 40mm Conserve A-class BFH femoral head, Ref. 30AM4035, Lot 1412848; a Profemur CoCr modular 12/14 short neck, Ref. PHAC1242, Lot 1632262; a size 6 Profemur Z titanium alloy femoral stem, Ref. PHA00270, Lot 1434096, and two 6.5mm cancellous bone screws, all of which were designed, manufactured, marketed and sold by the Defendant.

36. The surgeon who implanted Plaintiff's Wright Hip components did not violate any generally accepted standards of care in the field of orthopedic surgery in his care and treatment of the Plaintiff, either before, during, or after the hip implant surgery of April 7, 2014, nor did he negligently cause his injury.

37. Based upon the data provided by Wright Medical, Plaintiff was an appropriate

patient to be implanted with the Wright Medical Total Hip.

38. Based upon information provided by Defendant to Dr. Hanna concerning the benefits of the Device without disclosing the known risk of metallosis due to micromotion between the Wright Medical components, Dr. Hanna recommended the Wright Medical Hip System to the Plaintiff and indicated that the Device was appropriate for him.

39. Had Dr. Hanna been aware of the risks dating back to the early to mid-2000's when Wright Medical's Profemur components had failed due to fracture and/or metallosis, he would not have chosen or recommended those implants to the Plaintiff.

40. Plaintiff, Norman Mierke, reasonably relied upon Dr. Hanna's recommendations in deciding to be implanted with the Wright Medical Total Hip System.

41. On August 29, 2018, Mr. Mierke presented to Gonzalo Valdivia, MD, an orthopedist, with complaints of left hip pain and popping and constant subluxations when walking, bending and other activity. An x-ray taken that day showed dislocation of the acetabular liner with superior migration of the femoral head into the acetabulum. At that time, Dr. Valdivia referred Mr. Mierke to an orthopedic surgeon.

42. October 3, 2018, Mr. Mierke presented to Robert Blease, MD, an orthopedic surgeon upon Dr. Valdivia's referral. Dr. Blease noted that the x-rays of his left hip showed acute failure of the polyethylene acetabular liner. At that time, Dr. Blease recommended left hip revision surgery.

43. On October 16, 2018, Mr. Mierke underwent a total revision of his left hip replacement at Holmes Regional Medical Center in Melbourne, Florida by Dr. Blease. During that procedure, Dr. Blease found "*complete failure of the poly liner and severe metallosis". "There was [a] large loose poly fragment floating within the hip capsule as well*." Dr. Blease

removed all of the total hip components and implanted a Stryker Trident hip system with a Trident shell, a Trident poly insert, a ceramic femoral head, a Stryker Restoration femoral neck, a Restoration modular stem, a Dall-Miles trochanteric grip plate with two cables, and three additional Dall-Miles cable/sleeve sets. Post-revision pathology reported "sclerotic fibrovascular tissue with dense black pigment deposits.

44. Unfortunately, Mr. Mierke suffered complications after that surgery, which caused continuing left hip pain.

45. As a result of those complications, on February 13, 2020, Mr. Mierke underwent removal of the plate and cable hardware in his left hip at Holmes Regional Medical Center by John J. Perry MD to relieve that chronic pain.

46. As the result of these surgeries, Mr. Mierke is left with weakness and instability in his left hip.

47. As the direct result of the failure of the Wright Medical Profemur components, Mr. Mierke has suffered severe physical and mental pain and anguish, disability, inconvenience, and diminished ability to enjoy life, and has incurred substantial hospital, medical and rehabilitation expenses, and will continue to suffer these losses in the future.

48. Mr. Mierke, in the exercise of due diligence, could not have reasonably discovered the cause of his injuries including but not limited to, the defective design and/or manufacturing of the Device implanted inside of him until he underwent his first revision surgery on October 18, 2018.

Wrongful Conduct of Defendant

49. Defendant's hip components (the "Device") were intended to be used as a hip replacement for treatment of serious hip fractures or osteoarthritic hip conditions. Despite

Defendant's claims that this Device was safe and effective as a hip replacement, emerging scientific evidence suggests that the cobalt/chromium used in the Profemur modular femoral neck paired with the Profemur titanium alloy femoral stem was subject to fretting from micromotion at the trunnion junction which in turn, caused corrosion and sending micro metal debris and metallosis into the surrounding tissues, tendons, muscles and bone, which led to failure of the hip and caused severe injury to the patient.

50. At all relevant times, Defendant knew, or should have known, that the Device, which included two dissimilar metal alloys to be paired together would cause corrosion, metallosis and premature failure of the total hip system.

51. In addition, at all relevant times, Defendant knew or should have known the Device which included a Dynasty cup and Dynasty poly liner coupled with the Profemur modular neck, would cause the Dynasty liner to prematurely break apart and migrate and cause even more metallosis.

52. At all relevant times, Defendant's Device was marketed to the medical community and to patients as safe, effective, and reliable medical devices; and safer and more effective than traditional products or other competing hip replacement devices.

53. At all relevant times, Defendant marketed and sold its Device to the medical community and to patients via carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include aggressive marketing to health care providers which touted Defendant's Device to be less invasive and more effective than the competing devices.

54. Contrary to the Defendant's representations to the medical community and to the patients themselves, Defendant's Profemur Modular hip components with the CoCr modular neck and titanium alloy stem were defective in that they prematurely failed due to metallosis, and caused

severe injury to the patient, and required painful corrective surgery and a prolonged recovery time. Defendant consistently underreported and withheld information as to the propensity of the Device to fail; intentionally misled the medical community and consumers such as Plaintiff by underreporting adverse event reports and withholding information showing the propensity of the Device to fail; and intentionally misrepresented the efficacy and safety of the Device to the medical community, patients and the public at large.

55. At all relevant times, Defendant had actual knowledge, and continues to know, that some of the predicate products for the Device had high failure and complication rates; and/or that there were and are differences between the Defendant's Device and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that Defendant's representations to the medical community and to the public at large were incomplete and misleading as to significant differences between the Device and its predecessor and predicate products; and that the Device was causing injury and complications to numerous patients. Defendant suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or to patients. Defendant actively and intentionally misled the public and the medical community, and its patients, into believing that the Device and the procedures for the implantation were safe and effective in order to induce health care providers and patients to prescribe, implant and/or use the Defendant's Device.

56. Defendant improperly designed the Wright Medical Total Hip System by introducing two different metals to be paired with one another which they knew or should have known would cause a corrosive effect inside the human body and by designing acetabular components with a defective poly liner.

57. Defendant failed to perform adequate testing of the design of the Device and/or failed to rely upon test and study results concerning the efficacy of similar devices in order to determine and evaluate the risks and benefits of the Device before and after it was placed on the market.

58. Further, Defendant failed to implement adequate assembly procedures for the modular components of the Device.

59. In addition, Defendant falsely represented to the medical community and to the public at large, including Plaintiff, that the Device had been properly designed and tested and was found to be safe and effective for its use as a viable hip replacement.

60. Defendant also failed to design and establish a safe, effective procedure for removal of the Device in the event of failure, causing the Device to be impossible, or extremely difficult, to be safely removed from the body once implanted.

61. At all relevant times, feasible and suitable alternative total hip systems existed on the market.

62. Defendant's Device was at all times utilized and implanted in a manner foreseeable to the Defendant, as Defendant generated the instructions for use and created the procedure for implanting the device and trained the implanting physicians.

63. At all relevant times, Defendant provided incomplete, insufficient, and misleading training and information to the implanting physicians, in order to increase the number of physicians willing to choose Defendant's Device over an alternative device or procedure, in order to increase the sales of the Device, thereby causing the dissemination of inadequate and misleading information to be given to patients, including Plaintiff.

64. These misrepresentations and material omissions were made by Defendant with the

intent of inducing the medical community to recommend, prescribe, purchase and implant the Device for hip replacement, all of which evinced indifference to the health, safety and welfare of prospective consumers, including Plaintiff.

65. Defendant's Device that was implanted into Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendant, and in the condition directed by and expected by the Defendant.

66. At all relevant times, Defendant misrepresented to, and omitted and/or concealed from, Plaintiff and his implanting physician the following material information:

a. That the Device was not as safe as other products and procedures available for a viable hip replacement in the Plaintiff;

b. That the risk of adverse events with the Device was higher than with other total hip replacement systems;

c. That the risk of a cobalt chromium modular neck paired with a titanium allow stem exponentially raised the risk of corrosion, metallosis and metal debris to be disseminated into the surrounding tissues, causing injury to the patient;

d. That the high risk of metallosis from the mixed-metal femoral components created an unreasonably high risk of breakage, migration and failure of the Dynasty poly liner, which in turn created an even greater risk of metallosis injury.

e. That the risk of adverse events with the Device was not adequately tested either before or after it was marketed;

f. That the limited clinical testing which was done, revealed that the Device had a higher risk of adverse effects than those associated with other hip replacement products and procedures available;

g. That Defendant failed to follow up on the adverse results from clinical studies and concealed, minimized, or misrepresented those findings;

h. That Defendant was aware of the dangers presented by the Device, including a high incidence of trunnion corrosion caused by micromotion and chemical reaction of the dissimilar metals which caused corrosion and failure, and the need for revision surgery by the patient;

i. That patients who were implanted with the Device needed to be monitored closely

for possible complications and/or failure of the Device;

j. That the procedure to remove any one of the failed modular components of the Device had a high failure rate and/or risked removal of the entire hip replacement system or require excision of more bone and tissue from the patient, thereby reducing the success rate of revision surgery.

67. At all relevant times, Defendant had a duty when disseminating information to the public and to the medical community to disseminate truthful information; and a parallel duty not to deceive the public or Plaintiff, or his healthcare providers.

68. At all relevant times, Defendant had sole access to material facts concerning the defective design and/or nature of the Device and was under a duty to disclose to Plaintiff and his physicians the heightened risks of corrosion, trunnionosis, metal fatigue, metallosis damage, premature failure, and permanent injury caused by those defects.

69. At all relevant times, Defendant intentionally made material misrepresentations to the medical community and to the public, including Plaintiff, regarding the safety of the Device; specifically, that it was as safe or safer than other total hip replacement systems.

70. These representations, and others made by the Defendant, were false when made and/or were made with the pretense of actual knowledge, when such knowledge did not actually exist, and were made recklessly and without regard for the true facts.

71. Defendant's misrepresentations, and concealment and omissions of material facts concerning the risks of injury caused by the Device, were made to induce Plaintiff's physicians to purchase, prescribe and implant the Device into Plaintiff and/or to mislead Plaintiff into choosing that Device to replace his hip.

72. At the time Plaintiff was implanted with the Device, neither he nor his implanting physician were aware of the falsehood of Defendant's representations, and reasonably relied upon those representations, and Plaintiff was induced to using Defendant's device, causing him to suffer

severe, permanent injury and economic damages.

73. Had Plaintiff known the true facts about the dangers and serious health and safety risks of Defendant's Device, he would not have consented to having the Device implanted in him.

COUNT I – STRICT LIABILITY – DESIGN DEFECT

74. Plaintiff incorporates by reference paragraphs 1 through 73 of this Complaint as though fully set forth herein.

75. At all times material hereto, Wright Medical engaged in the business of designing, developing, manufacturing, testing, packaging, labeling, marketing, selling, and/or distributing, the Wright Medical Total Hip System with Dynasty acetabular components, and the Profemur metal-on-metal femoral components.

76. The Device was intended for use in hip replacement procedures for consumers, and Plaintiff, Norman Mierke, was a consumer and relied upon the manufacturing safety of the Device.

77. At all relevant times, Defendants expected the Wright Medical Hip System to reach, and it did reach, consumers including Plaintiff, without substantial change in the condition in which it was sold.

78. The Wright Medical Profemur femoral components were defectively designed, manufactured, and/or tested so as to be unreasonably dangerous to consumers and to Plaintiff at the time it was placed into the stream of commerce, in that:

a. When placed in the stream of commerce, the components contained an unreasonably dangerous design which, by its very nature, created a unreasonably high risk of corrosion and metallosis, and was not reasonably safe as intended to be used, subjecting the Plaintiff to failure of his total hip replacement, severe injury, and the necessity of further invasive surgery;

b. The Profemur components, when used in a proper and foreseeable manner were not as safe as the Plaintiff expected;

c. The Dynasty acetabular components with the poly liner, when used in a proper and foreseeable manner were not as safe as the Plaintiff expected;

d. When placed in the stream of commerce, the Device created unreasonably high risk of failure which exceeded the benefits of the device;

e. When placed in the stream of commerce, the Device was more dangerous than an ordinary consumer would expect and more dangerous than other similar prosthetic hip components that were already on the market;

79. The Profemur femoral components that were implanted into the Plaintiff as part of his total hip replacement had not been materially altered or modified prior to the implantation of the device.

80. Plaintiff was a foreseeable user of the device and the device was implanted into him for its intended purpose, a total hip replacement.

81. Had the design of the Profemur modular neck and Profemur stem not been defective, along with the defective Dynasty components, Plaintiff would not have sustained the injuries alleged herein.

82. As the direct and proximate result of the defective design of the Wright Medical Total Hip System, Plaintiff, Normal Mierke, was implanted with Device on April 7, 2014 and suffered painful failure of his left hip replacement just four years later, which required a complex left hip revision and a second surgery to remove hardware that was necessary for that revision, all of which has caused him to suffer ongoing injury.

83. As a further proximate result of the defective design of the Wright Medical Hip System, Plaintiff has suffered debilitating physical pain and mental suffering; incurred substantial hospital, medical, nursing, rehabilitative, pharmaceutical and other expenses therefrom; and lost quality of life, and all of these injuries are permanent and continuing.

84. Defendant is strictly liable to Plaintiff for the design of the defective product.

COUNT II – STRICT LIABILITY – MANUFACTURING DEFECT

85. Plaintiff incorporates by reference Paragraphs 1 through 73 of this Complaint as though fully set forth herein.

86. At all relevant times, Defendant, Wright Medical, manufactured, designed, distributed, and/or sold the Wright Medical Dynasty acetabular components, and the Profemur femoral hip components that were implanted into the Plaintiff, Norman Mierke, as part of his left total hip replacement.

87. The Device was intended for use as total hip replacements for consumers, and Plaintiff was a consumer who relied upon the manufacturing safety of the device.

88. At all relevant times, Defendant expected the Device to reach, and it did reach, consumers, including Plaintiff, without substantial change in the condition in which it was sold.

89. The Device that was manufactured, designed, marketed, distributed, sold and/or placed in the stream of commerce by the Defendant was defective in its manufacture and construction in that, when it left the hands of the Defendant, it deviated from product specifications and/or applicable federal requirements for these medical devices, in that the cobalt chromium modular neck, paired with a Profemur titanium alloy stem, posed an unreasonable risk of corrosion, metallosis and severe injury to the consumer into whom it was implanted.

90. Specifically, the Device was manufactured by pairing two different metals together which, when inserted into the human body, begins a corrosion process, which disseminates micro metal particles into the surrounding tissue, muscle and tendons of the hip, which destroys those surrounding tissues and muscles, resulting in permanent injury to the patient. In addition, those metal particles enter the bloodstream of the patient, creating systemic

issues such as headaches, blurred vision and cognitive impairment.

91. The Device was also defective in that the Dynasty poly liner deviated from product specifications by breaking apart and migrating out of the Dynasty shell and prematurely failing after being used in a reasonably foreseeable manner.

92. Plaintiff was a foreseeable user of the Device and the Device was implanted into him for its intended purpose, i.e. components of a total hip replacement, and was not as safe as any reasonable consumer would expect.

93. Had the Wright Medical Profemur Hip System not been defectively manufactured, Plaintiff would not have sustained the injuries alleged herein.

94. As the direct and proximate result of the defective manufacture of the Wright Medical Hip System, Plaintiff Norman Mierke was implanted with the Device on April 7, 2014 and suffered painful failure of his left hip replacement, required a left hip revision, and required a second surgery to remove hardware from the revision surgery.

95. As a further proximate result of the defective manufacture of the Wright Medical Device, Plaintiff has suffered debilitating physical pain and mental suffering; incurred substantial hospital, medical, nursing, rehabilitative, pharmaceutical and other expenses therefrom; and lost quality of life, and all of these injuries are permanent and continuing.

96. Defendant is strictly liable to Plaintiff for manufacturing a defective product.

COUNT III – STRICT LIABILITY – FAILURE TO WARN

97. Plaintiff incorporates by reference Paragraphs 1 through 73 of this Complaint as though fully set forth herein.

98. At all relevant times, the Wright Medical Profemur modular cobalt chromium neck and Profemur titanium alloy stem that were implanted in the Plaintiff presented an unreasonable

risk of failure and injury that was known, or should have been known, to the Defendant and could not readily be known to the Plaintiff or his implanting surgeon.

99. At all relevant times, Defendant failed to warn Plaintiff or his implanting surgeon that the Profemur components were more likely to suffer corrosion and metallosis than other femoral components which were available on the market.

100. At all relevant times, Defendant failed to warn Plaintiff or his implanting surgeon that the Profemur components made with two dissimilar metals, when paired together, created an unreasonably high risk of elevated metal ions, metallosis and the need for premature revision surgery.

101. At all relevant time, Defendant failed to warn Plaintiff or his implanting surgeon that the titanium Dynasty liner created an unreasonably high risk of breakage, migration, metallosis, and failure when coupled a CoCr Conserve head and Profemur modular neck.

102. In light of Defendant's failure to warn of the defects and risks associated with the Device that was implanted in Plaintiff, the Device was not reasonably safe for its intended use, was not as safe as a reasonable consumer would expect, and was defective as a matter of law due to its lack of appropriate and necessary warnings.

103. As a direct and proximate result of Defendant's failure to warn, or promptly and adequately warn, Plaintiff about the defects in the Device, Plaintiff was caused, and/or in the future will be caused, to suffer severe personal injuries, pain and suffering, emotional distress, financial or economic loss including, but not limited to, obligations for medical services and expenses, and other damages.

104. Defendant is strictly liable to Plaintiff for its failing to warn Plaintiff or his implanting surgeon of a defective product.

COUNT IV - NEGLIGENCE

105. Plaintiff incorporates by reference paragraphs 1 through 73 of this Complaint as though fully set forth herein.

106. At all relevant times, Defendant Wright Medical owed a duty to consumers, including Plaintiff, Norman Mierke, to use reasonable care in the design, manufacturing, testing, packaging, labeling, selling and distribution of the Wright Medical Hip System with the Dynasty and Profemur components.

107. Defendant breached that duty and was negligent by failing to use reasonable care in the design, manufacture, testing, packaging, labeling, marketing and sales of the components in that, when correctly implanted and used as intended, they corroded and failed, causing metallosis and extreme pain to the Plaintiff and requiring Plaintiff to undergo a revision hip surgery and a second surgery to remove hardware from the revision surgery.

108. As a direct and proximate result of Defendant's negligence, Plaintiff was caused, and/or in the future will be caused, to suffer severe personal injuries, pain and suffering, emotional distress, financial or economic loss including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT V – FRAUDULENT MISREPRESENTATION

109. Plaintiff incorporates by reference Paragraphs 1 through 73 of this Complaint as though fully set forth herein.

110. At the time Plaintiff was implanted with the Wright Medical Profemur femoral components, Defendant had actual knowledge that corrosion was likely to occur between the Profemur cobalt chromium modular necks and the Profemur titanium alloy femoral stem due to the metal dissimilarities.

111. Also, at the time Plaintiff was implanted with the Wright Medical Profemur femoral components, Defendant had actual knowledge that corrosion was likely to occur between the Profemur cobalt chromium modular necks and the Profemur titanium alloy femoral stem due to plaintiff/surgeon complaints and/or adverse event reports.

112. Despite that knowledge, Wright Medical not only failed to warn the health community and the public about those material facts, Defendant proactively and aggressively marketed the Profemur components as safer and longer-lasting than other hip components on the market.

113. In addition, prior to Plaintiff's implant in 2014, Wright Medical had actual knowledge that the Dynasty shell and poly liner, combined with the Profemur modular neck, created a high risk of premature breakage, migration and failure of the liner.

114. The conduct of the Defendant, which viewed objectively from Defendant's standpoint at the time of its occurrence, involved an extreme degree of risk considering the probability and magnitude of the potential harm to consumers, including Plaintiff.

115. Defendant had actual, subjective awareness of the risks involved with respect to its conduct, but nevertheless proceeded with conscious indifference to the rights, safety and welfare of others, and acted with an evil mind to serve its own interest, having reason to know and consciously disregarding a substantial risk that its conduct might significantly injure the rights of others, including Plaintiff, and consciously pursued a course of conduct knowing that it created a substantial risk of significant harm to others, including Plaintiff.

116. The acts, omissions, or both of the Defendant that constituted intentional wrongdoing and/or gross negligence include, but are not limited to, one or more of the following:

a. designing and using components in the manufacture of the Device that led to crevice corrosion, due to the press fit nature of the modular implant and the materials used in

the modular femoral neck which, coupled with the progressive wear of the surface due to its use, resulted in fretting, corrosion and failure of the neck/stem junction and caused severe metallosis and severe injury to the Plaintiff;

b. Designing and using a poly liner that did not stand up to a CoCr femoral head and Profemur trunnion corrosion;

c. failing to conduct adequate premarket or post-market testing of the Device;

d. failing to properly market the Device;

e. failing to warn of the unreasonably high risks of corrosion, failure and metallosis posed by the Device.

117. Defendant knew that there was a high probability that the Wright Medical Hip System at issue would corrode, and fail, due to the press fit nature of the modular implant, due to the materials used in the implant, and due to the lack of warning to patients or their implanting surgeons concerning the weight tolerance of the implant.

118. Despite that knowledge, Defendant nevertheless proceeded with conscious indifference to the rights, safety and welfare of consumers in general, including the Plaintiff.

119. As a direct result of Defendant's willful and intentional or grossly negligent conduct, Plaintiff's surgeon was not made aware of the unreasonable risk of corrosion and metallosis posed by the components and Plaintiff was implanted with the Wright Medical Hip System with those components to his detriment.

JURY DEMAND

Plaintiff hereby requests a trial by jury.

PRAYER

WHEREFORE, Plaintiff prays that Defendant be summoned to appear and answer herein, and that upon final trial, Plaintiff be awarded judgment against Defendant for:

a) Compensatory, special and general damages in an amount above the minimum jurisdictional limits of this Court;

b) Punitive damages in an amount to be determined by the Court;

c) Post-judgment interest;

d) Reasonable costs of the prosecution of this claim;

d) Any such other and further relief to which Plaintiff may be justly entitled.

Dated this 24th day of July, 2020.

_s/ Joseph H. Saunders_____
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